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RESEARCH

Safety with the senhance™ robotic system in 3,239 patients across various surgical disciplines

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Abstract

Purpose At present, robotic surgery has found its most frequent application in gastrointestinal, gynaecological, and urological procedures, presenting a seamless integration of advanced technology. The Senhance™ Robotic System certainly contributes to this evolution, gracefully employed to enhance precision and efficacy in these surgical disciplines. However, safety data, such as conversion rates, robotic malfunctions, and adverse event rates, are still lacking on a large scale.

Methods To shed light on this, data from nine European centres (N=3,239) was collected prospectively as part of the TRUST registry.

Results Our results present most data from gastrointestinal surgery (2,132 cases), followed by procedures from gynaecology (609 cases) and urology (498 cases). Overall, we found a conversion rate of 4.5% (147 cases). Robotic malfunctions were seen in 3% (96 cases) of the procedures, with console malfunctions occurring in 0.5% (16 cases), monitor or camera issues affecting 0.5% (17 cases), and other malfunctions registered in 2.1% (69 cases). The most common robotic limitations were displayed by limited motion (15.6%, 505 cases) and collisions (6.2%, 202 cases). Finally, we found a 3.9% rate of adverse events, with 127 episodes across all three disciplines. Most adverse events were judged as mild in severity (53 cases) and unrelated (101 cases) to the robotic system. Additionally, only one case was considered to be certainly related to the Senhance™ Robotic System, and just three serious adverse events occurred intraoperatively.

Conclusion In conclusion, our data demonstrates that performing gastrointestinal, gynaecological, and urological surgeries with the Senhance™ Robotic System can be safe for patients and surgeons.

Keywords Robotic surgery · Senhance™ robotic system · Safety in surgery · Minimally invasive surgery

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Introduction

Since the beginning of the 21 st century, the landscape of surgical practice has advanced with wide applications of robotic surgical systems. General/visceral surgery, gynaecology, and urology are certainly three of the most prevalent surgical disciplines that have implications for robotic surgery [1]. Therefore, data on robotic surgery is gradually accumulating, with recent literature providing insights into various aspects of robotic surgery based on diverse robotic systems and compared to open and laparoscopic approaches [2, 3]. To illustrate the trend, robotic surgery offers potential benefits such as improved intraoperative precision, reduced pain and shorter recovery times postoperatively [1]. Even as this technology becomes widely adopted, safety concerns remain, particularly among surgeons and patients. Consequently, the focus on safety and related aspects, such as adverse events, remain crucial for investigations. As there is a vast amount of surgical robots in the constantly growing market, our focus is directed towards the Senhance™ Robotic System, formerly known as TransEnterix (Asensus Surgical US, Inc., Durham, NC, USA), as shown in Fig. 1. Despite encouraging results reported in recent literature [4], the absence of a comprehensive big data analysis limits our understanding of the safety profile of this robotic system. It is, hence, essential to investigate the factors contributing to safety in robotic procedures, especially across various disciplines. By doing so, the role of the robot, in terms of robotic malfunctions and limitations, and the surgical performance, such as the adverse events and conversions, should be explored and discussed. This paper aims to fill the gap of missing big data and contribute to the growing body of evidence by evaluating outcomes from procedures deriving from gastrointestinal, gynaecological, and urological surgery with the Senhance™ Robotic System. We aim not to focus on a single discipline but to provide condensed insight across disciplines in different countries. Our primary focus is on investigating conversions, robotic malfunction and limitations, and (serious) adverse events (AE) recorded during robotic surgeries utilising the Senhance™ Robotic System at nine European centres. By systematically analysing safety outcomes across multiple European sites, we aim to provide valuable insights into the safety profile of the Senhance™ Robotic System.

Materials and methods

Patients

Patients were included as participants if they were suitable for laparoscopy in gastrointestinal surgery, gynaecology, or urology, and robotic surgery was equally performable. They were recruited and screened at nine European centres (Feldkirch State Hospital, Feldkirch, Austria; Klaipeda University Hospital, Klaipeda, Lithuania; Sana Hospital Offenbach, Offenbach, Germany; St.-Marien Hospital Siegen, Siegen, Germany; University Hospital Centre Zagreb, Zagreb, Croatia; Evangelical Hospital Wesel, Wesel, Germany; LAKUMED Hospital, Landshut-Achdorf, Germany; Evangelical Hospital Goettingen-Weende, Göttingen-Weende, Germany and Hospital Esslingen, Esslingen Germany). All centres are part of the TRUST study (The TransEnterix European Patient Registry for Robotic-assisted Laparoscopic Procedures in Urology, Abdominal Surgery, Thoracic and Gynecologic Surgery), representing an international study group. An insight into current active sites can be found in Supplementary Table 1. The inclusion of the present study followed the TRUST study guidelines. Patients had to have an indication for surgery in the respective gastrointestinal, gynaecological, or urological departments and no absolute contraindications (e.g.,

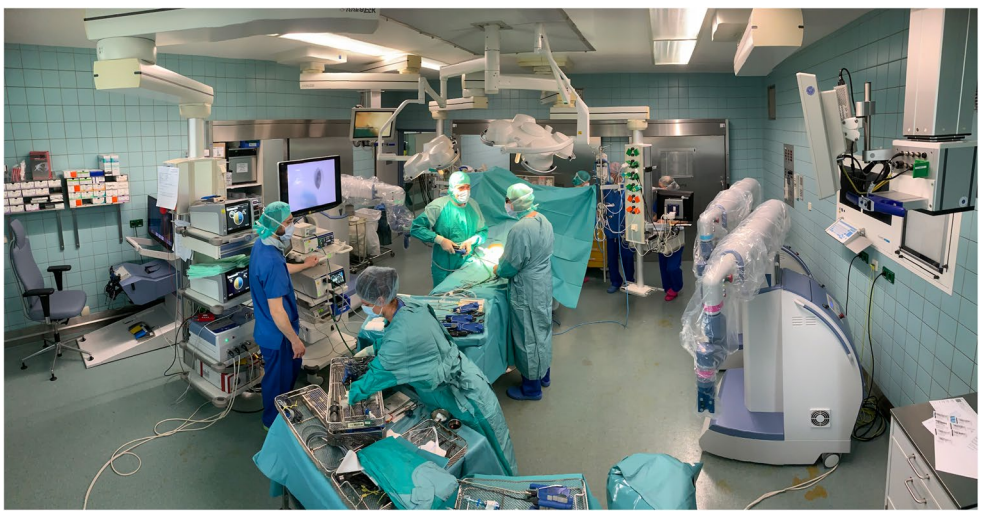

Fig. 1 Senhance™ robotic system with console and three arms

cardiopulmonary diseases hindering general anaesthetics for robotic surgery or expected severe intraabdominal adhesions). Exclusion criteria were represented by the inability to give informed consent, any contraindication for laparoscopy, and life-threatening conditions. Each patient provided written informed consent for the robotic surgery procedure, which was documented and recorded in a database. Confidentiality and anonymity of patient data were strictly maintained. The study was approved by the Ethics Committee of the Medical Association of Westphalia-Lippe and the University of Münster (Approval Number: 2017-463-f-S) and was subsequently confirmed by several local approvals.

Procedure

All procedures were performed in the nine European centres' gastrointestinal surgery, gynaecology, and urology departments (as stated above). Various procedures were recorded, but the current paper does not intend to display procedural details. The training for performing surgeries with the Senhance™ Robotic System always involves an initial introduction to the robotic platform followed by a two-day dry lab session and a three-day wet lab session. Following these sessions, surgeons perform various procedures on pig models under the guidance and mentorship of certified, experienced surgeons for three days. Across all centers, 49 trained cockpit surgeons performed all the surgeries, accompanied by 93 trained assistants. The system and setup information can be found as described by Stephan and colleagues [5], and illustrations can be found by Staib and colleagues [4]. Surgical procedures were completed totally using the Senhance™ Robotic System if not stated otherwise. If the procedure needed conversion, continuation via laparoscopic approach, open or first laparoscopic and then open approach, was registered in the database. Regarding technical aspects, device deficiencies such as robotic malfunctions and limitations were protocolled and specified. Device deficiency refers to any inadequacy in the robotic system's identity, quality, durability, reliability, safety, or performance. Additionally, for each surgical procedure, the occurrence of an AE was documented, specified, and described. By study design, intraoperative and postoperative (within 30 days after the procedure) complications were defined as AE. These refer to any unexpected health problem, such as diseases, injuries, or abnormal test results, regardless of whether they were linked to the robotic system. In case of a serious adverse event (SAE), surgeons applied the Good Clinical Practice [6]. In context, any complication that led to death or serious health impairment, such as life-threatening illness or injury, permanent impairment of body structures or functions, re-hospitalisation or prolongation of hospitalisation, re-intervention, or chronic disease, was meant to be categorised as an SAE. AEs were further categorized in severity (mild, moderate, and severe) and whether the event was causal to the robotic system. It is important to note that AEs related to the robotic system and those related to the procedures were recorded. An AE can be, however, related to both the robotic system and the procedure. Four levels present the causality: 1. "certain" 2. probable" 3. "possible" 4. "unlikely/not related". "Not related" is defined as not correlating with device use and may involve other causes; "Possible" as a weak relationship with alternative causes plausible; "Probable" as likely related to device or procedures; and "Causal" as strongly associated with the device or procedures, with alternative causes ruled out. A safety committee reevaluated the connection and causality to the robotic system. Study initiation started in May 2018. The data extraction from registry databases ended in February 2024.

Statistical evaluation was performed with „statistical software SAS® 9.4 (TS1M6) for Microsoft Windows" [7]. Numerical data that followed normal distribution was displayed as mean and standard deviation (SD). Otherwise, a median and IQR (interquartile ranges) presentation was chosen. Categorical data is demonstrated as numbers (N) and percentages (%).

Results

Patients

In total, 3,239 patients underwent gastrointestinal, gynaecological, and urological surgery procedures with the Senhance™ Robotic System. The average patient age was 57.6 years (SD: 13.9). The study population consisted of 51.6% males and 48.4% females, with an average BMI of 26.5 kg/m² (SD: 6.1). Most of the patient population (78.1%) did not present a history of smoking. However, 47.2% of them had chronic diseases, and 32.1% had undergone previous abdominal surgery. An overview is presented in Table 1.

Indications for undergoing surgery with the Senhance™ Robotic System were diverse. Most data were derived from gastrointestinal surgery (2132 cases), followed by procedures from gynaecology (609 cases) and urology (498 cases). A total of 34 different procedure types were carried out, with data gathered from cholecystectomy, inguinal hernia repair, fundoplication, and radical prostatectomy being the most frequently reported. All surgical procedures are displayed in Table 2.

Table 1 Demographic data and comorbidity of all patients operated with the senhance™ robotic system across all three surgical disciplines

Parameter		Gastrointestinal	Gynaecological	Urological	Total
	N	2,132	609	498	3239
Age (years)	mean ± SD	58.4 ± 14.5	50.4 ± 13.0	63.2 ± 6.9	57.6 ± 13.9
Gender	Male	1175 (55.2%)	3 (0.5%)	491 (98.8%)	1669 (51.6%)
	Female	954 (44.8%)	606 (99.5%)	6 (1.2%)	1566 (48.4%)
BMI (kg/m²)	mean ± SD	26.7 ± 6.6	25.1 ± 5.8	27.6 ± 3.4	26.5 ± 6.1
History of smoking	No	1,639 (79.3%)	475 (78.0%)	353 (73.2%)	2467 (78.1%)
	Yes	428 (20.7%)	134 (22.0%)	129 (26.8%)	691 (21.9%)
Relevant diseases	No	928 (44.0%)	493 (81.0%)	277 (55.6%)	1698 (52.8%)
	Yes	1,182 (56.0%)	116 (19.0%)	221 (44.4%)	1519 (47.2%)
Relevant diseases (multiple entries)	Diabetes	102 (4.8%)	10 (1.6%)	37 (7.4%)	149 (4.6%)
	Hypertension	613 (28.8%)	33 (5.4%)	157 (31.5%)	803 (24.8%)
	Cardiovascular Co-morbidity	227 (10.6%)	15 (2.5%)	27 (5.4%)	269 (8.3%)
	COPD or Impaired Respiratory Function	141 (6.6%)	10 (1.6%)	4 (0.8%)	155 (4.8%)
	Impaired Renal Function	61 (2.9%)	2 (0.3%)	3 (0.6%)	66 (2.0%)
	Liver Disease	25 (1.2%)	1 (0.2%)	4 (0.8%)	30 (0.1%)
	Stroke	16 (0.8%)	4 (0.6%)	3 (0.6%)	23 (0.7%)
	Sleep Apnea	24 (1.1%)	-	3 (0.6%)	27 (0.8%)
	GERD	375 (17.6%)	2 (0.3%)	7 (1.4%)	384 (11.9%)
	Depression	52 (2.4%)	19 (3.1%)	9 (1.8%)	80 (0.2%)
	Osteoarthritis	21 (1.0%)	1 (0.2%)	8 (1.6%)	30 (0.1%)
	Chronic pain	22 (1.0%)	1 (0.2%)	4 (0.8%)	27 (0.1%)
	Others	507 (23.8%)	61 (10.0%)	55 (11.0%)	623 (19.23%)
Relevant previous abdominal surgery	No	1,281 (60.5%)	487 (80.0%)	421 (84.5%)	2189 (67.9%)
	Yes	836 (39.5%)	122 (20.0%)	77 (15.5%)	1035 (32.1%)
Relevant abdominal surgeries (multiple entries)	Open	425 (19.9%)	62 (10.2%)	66 (13.3%)	553 (17.1%)
	Laparoscopic	428 (20.1%)	68 (11.2%)	16 (3.2%)	512 (15.8%)

Conversion and robotic malfunction

As one of the most important findings in the present paper, based on data from 3,239 procedures, only a minority of cases (4.5%, 147 cases) needed a conversion, as summarized in Table 3. Specifically, 2.4% (79 cases) required conversion to a laparoscopic approach, while 1.8% (59 cases) continued with open surgery, and 0.3% (9 cases) began laparoscopically but needed finalisation by open surgery.

Robotic malfunctions were observed in 3% of the cases (96 cases), including six episodes of multiple errors during a single procedure. Console malfunctions occurred in 0.5% of the cases (16 cases), while issues with the monitor or camera also affected 0.5% (17 cases). Other malfunctions were noted in 2.1% (69 cases), encompassing difficulties regarding eye tracking, connecting robotic arms to the console, and problems with robotic instruments (e.g., bipolar scissors, ultrasound, and needle holders). The most common robotic limitations were displayed by limited motion (15.6%, 505 cases) and collisions (6.2%, 202 cases). Life-threatening situations were never observed.

Adverse events

As a second major finding, we observed AEs in 3.9% of the cases, totaling 127 instances. Table 4 summarises AE categories, with percentages in relation to the total 127 cases. The most common AEs were haemorrhage (19 cases), wound complications (9 cases), postoperative ileus (6 cases), and symptomatic seroma (6 cases), as well as AEs categorised as “others” (58 cases). Category “others” most often included reportings such as hematoma, pain, hernia, and (minimal) anastomotic leakage or stenosis, which were primarily treated conservatively. Importantly, no mortality was reported. Most AEs were mild in severity (1.6%, 53 cases), followed by moderate (1.4%, 44 cases) and severe AEs (0.9%, 30 cases). Regarding causality, the majority of cases were deemed unrelated to the robotic system (79.5%, 101 cases), with a smaller proportion categorised as possible (15.7%, 20 cases), a minority as probable (3.1%, 4

Table 2 Surgical procedures of all patients operated with the senhance™ robotic system across all three surgical disciplines

Gastrointestinal		Gynaecological		Urological	
2132		609		498	
Cholecystectomy	447 (21.0%)	Ovarian cyst enucleation	54 (8.9%)	Radical prostatectomy	488 (98.0%)
Inguinal Hernia Unilateral	496 (23.3%)	Ovarian endometriosis	23 (3.8%)	Lymph node dissection	1 (0.2%)
Inguinal Hernia Bilateral	201 (9.4%)	Monolateral salpingectomy	24 (3.9%)	Partial nephrectomy	3 (0.6%)
Ventral Hernia	10 (0.5%)	Bilateral salpingectomy	19 (3.1%)	Adrenalectomy	6 (1.2%)
Fundoplication	477 (22.4%)	Monolateral oophorectomy	6 (1.0%)		
Sigmoid Resection/ Left Hemicolectomy	200 (9.4%)	Bilateral oophorectomy	2 (0.3%)		
Rectal Surgery	136 (6.4%)	Monolateral salpingo-oophorectomy	18 (3.0%)		
Functional rectal surgery	16 (0.8%)	Bilateral salpingo-oophorectomy	31 (5.1%)		
Implant of an electric stimulator	8 (0.4%)	Total Hysterectomy	312 (51.2%)		
Bariatric procedures	6 (0.3%)	Radical hysterectomy	26 (4.3%)		
Gastric resection	5 (0.2%)	Supracervical hysterectomy	28 (4.6%)		
Right Hemicolectomy	66 (3.1%)	Pelvic lymphadenectomy	3 (0.5%)		
Liver surgery	4 (0.2%)	Sentinel node mapping	3 (0.5%)		
Other	58 (2.7%)	Sacrocolpopexy	1 (0.2%)		
		Myomectomy	27 (4.4%)		
		Adhesiolysis	32 (5.3%)		

Table 3 Conversion and robotic malfunctions of all patients operated with the senhance™ robotic system across all three surgical disciplines

Parameter		Gastrointestinal	Gynaecological	Urological	Total
	N	2,132	609	498	3,239
Conversion	No	2,009 (95.2%)	592 (97.2%)	467 (94.2%)	3,068 (95.4%)
	Laparoscopic	41 (1.9%)	11 (1.8%)	27 (5.4%)	79 (2.5%)
	Open	54 (2.6%)	3 (0.5%)	2 (0.4%)	59 (1.8%)
	Laparoscopic + Open	6 (0.3%)	3 (0.5%)	-	9 (0.3%)
Robot malfunctions	No	2,071 (97.1%)	594 (97.5%)	478 (96.0%)	3,143 (97.0%)
	Yes	61 (2.9%)	15 (2.5%)	20 (4.0%)	96 (3.0%)
Robot malfunction (multiple entries, percentage based on all patients)	Console malfunction	7 (0.3%)	8 (1.3%)	1 (0.2%)	16 (0.5%)
	Monitor/camera malfunction	10 (0.5%)	3 (0.5%)	4 (0.8%)	17 (0.5%)
	Other malfunction	48 (2.3%)	6 (1.0%)	15 (3.0%)	69 (2.1%)
Robot limitations	Limited motion	251 (11.8%)	138 (22.7%)	116 (23.3%)	505 (15.6%)
	Collision	129 (6.1%)	37 (6.1%)	36 (7.2%)	202 (6.2%)

Laparoscopic Laparoscopic approach, *Open* Open approach

cases), and only (0.8%, 1 case) as certain. This certain relationship was found in a patient who returned to the hospital with a bolus obstruction of the lower esophagus 5 days after robotic fundoplication. An esophageal perforation was diagnosed. The situation had to be corrected and repaired in a second intervention. According to the regulations on causality reporting, this had to be reported as a certain relation, whereby the procedural relation and the robotic relation are supposed to be reported at the same level, since, in hindsight, the immediate causality could not be assessed anymore.

Serious adverse events (SAEs) were reported in 44 cases (34.6%, 1.4% of the overall cases), with 29 cases registered before discharge from the hospital and 15 after discharge. The majority were documented from gastrointestinal surgeries (37 cases, 1.7% of all gastrointestinal processes), while gynaecology counted 5 cases (0.8% of all gynaecological processes) of SAEs and urology only 2 cases (0.4% of all urological procedures). A total of 3 SAEs were recorded

Table 4 Adverse events of all patients operated with the senhance™ robotic system across all three surgical disciplines

		Gastrointestinal (*N*= 2,132)	Gynecological (*N*= 609)	Urological (*N*= 498)	Total (*N*= 3,239)
	Number of AEs	102	8	17	127
Adverse event category (multiple entries)	Hemorrhage	14 (13.7%)	2 (25%)	3 (17.6%)	19 (15%)
	Wound complication	9 (8.8%)	0 (0%)	0 (0%)	9 (7.1%)
	Postoperative ileus	4 (3.9%)	1 (12.5%)	1 (5.9%)	6 (4.7%)
	Symptomatic seroma	5 (4.9%)	0 (0%)	1 (5.9%)	6 (4.7%)
	Urological injury	3 (2.9%)	2 (25%)	0 (0%)	5 (3.9%)
	Urine tract infections	0 (0%)	1 (12.5%)	4 (23.5%)	5 (3.9%)
	Internal organ damage	4 (3.9%)	0 (0%)	0 (0%)	4 (3.1%)
	Urinary retention	1 (1.0%)	1 (12.5%)	1 (5.9%)	3 (2.4)
	Myocardial infarction	2 (2.0%)	0 (0%)	1 (5.9%)	3 (2.4%)
	Biliary duct injury	1 (1.0%)	0 (0%)	0 (0%)	1 (0.8%)
	Small bowel obstruction	1 (1.0%)	0 (0%)	0 (0%)	1 (0.8%)
	Other	58 (56.9%)	1 (12.5%)	6 (35.3%)	65 (51.2%)

Percentages in relation to Number of AEs

during surgery. In Table 5, all (peri- and postoperative) SAEs are displayed and summarised into categories. For instance, SAEs include internal organ damage such as intestinal leakage or abscess, stomach perforation due to adhesions or auxiliary trocar placement, esophagus perforation during gastric tube placement, and colon perforation due to diverticulum with coprostasis. Hemorrhage was caused by anticoagulation medication or bleeding vessels (e.g., from the vagina or anastomosis). Small bowel obstructions and lesions were due to adhesive ileus or adhesions.

Discussion

Patient-related safety parameters are essential when new technologies are introduced into surgical practice. Our current study explored significant safety aspects in robotic-assisted surgery utilising the Senhance™ Robotic System in various gastrointestinal, gynaecological, and urological procedures.

Robotic surgery with the Senhance™ Robotic System promises advanced capabilities for minimally invasive procedures, empowering surgeons with improved precision and dexterity. To illustrate, the Senhance™ Robotic System has additional, integrated safety benefits that have not been available so far in general laparoscopy. Including an eye tracker for the camera, which the surgeon is maneuvring himself (and not his assistant), provides enhanced situational awareness, control and precision in movements within the surgical field. Moreover, 3-D visualisation allows the surgeon to closely examine and assess structures, similar to what an open approach could achieve. Finally, tactile feedback adds to the surgeon's experience and helps to evaluate the strength between instruments and tissue by sensory feedback, comparable to what is experienced in open and laparoscopic surgery. These features were designed to enhance the confidence and performance of the surgeon and, most importantly, perhaps also patient safety outcomes. Our results underscore this with a minimal conversion rate of 4.5%, however, in a selected patient cohort. In the present literature, similar conversion rates are described. Studies by Farah and colleagues [8] and Abd El Aziz and colleagues [9] illustrated substantial cohorts with mean conversion rates of 4.3% and 4.9%, respectively. Both rates were significantly less than the findings for laparoscopy (9.2% and 8.5%, respectively, both $p < 0.001$). However, robotic cases are typically more carefully selected than laparoscopic cases, which are often performed in emergency situations (e.g., acute appendicitis, organ perforation, complicated diverticulitis). To put conversion rates further into context, we need to stress the fact that the decision to switch to alternative approaches can arise from various factors. Evaluating our patient data, an increased average BMI (26.5 kg/m² ± 6.1) and previous abdominal surgery with adhesions in 32.1% of the cases likely contributed to limited intraabdominal space, higher instrument and camera leverages, and impaired vision of the intraoperative situs [10, 11].

Interestingly, no robotic malfunction led to a conversion, and robotic limitation mostly did not cause a shift to another approach. It is important to highlight that robotic limitations can be resolved in the majority of cases. Typically, limited motion serves as an informational warning that experienced surgeons can effectively manage. However, collision is a "real world" limitation, as the robotic arms sometimes get stuck and need manual help to be entangled. This can be achieved by either the assistant or a nurse in the operating room (OR). In addition, arm collisions can be avoided by choosing a different camera (e.g.,. 0 degrees instead of 30 degrees in inguinal hernia) or optimal trocar positions. The

Table 5 Serious adverse events of all patients operated with the senhance™ robotic system across all three surgical disciplines

Complication	Management	Number of Events	Causality
Internal organ damage - lesion in small intestine	Reoperation	2	3
Internal organ damage - lesion in small intestine	Reoperation	1	4
Internal organ damage - perforation	Reoperation	1	1
Internal organ damage - perforation	Reoperation	5	4
Hemorrhage	Reoperation	2	3
Hemorrhage	Reoperation	5	4
Hemorrhage/hematoma	Conservative	2	4
Hemorrhage	Endoscopic intervention	1	4
Small bowel obstruction	Reoperation	1	2
Stenosis	Endoscopic intervention	1	3
Postoperative ileus	Reoperation	4	4
Anastomotic leakage	Conservative	4	4
Anastomotic leakage	Reoperation	1	4
Myocardial infarction	Minimally invasive procedure	3	4
Pain and dyspnoea	Conservative	1	3
Cognitive issues	Conservative	1	4
Biliary peritonitis	Conservative	1	4
Pelvic peritonitis	Conservative	1	4
Suture insufficiency	Reoperation	1	3
Intraoperative cardiac insufficiency	Two-stage procedure	1	4
Gastroenteritis	Conservative	1	4
Urological injury	Reoperation	1	2
Respiratory insufficiency, acidosis, hypercapnia	Conservative	1	4
Urinary retention/Necrosis of the colon brought to the small pelvis	Reoperation	1	4
Subhepatic abscess	Reoperation	1	4

Casualty to the robotic system: 1. "certain" 2. probable" 3. "possible" 4. "unlikely/not related"

recently published investigations on the learning curve with the Senhance™ Robotic System by Menke and her team indicate that after approximately 30 procedures, aspects such as trocar position, robotic arm position, and surgical time have shown improvement [12]. Overall, the rate of robotic malfunction (2.1%) appears to fall within a reasonable range when compared, for instance, to a study investigating 10,000 cases performed with the da Vinci Robotic Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA) by Koh and colleagues (1.8%) [13].

Given these scenarios, the learning process for surgeons is an important aspect of safety in robotic surgery [14]. Structured training programs could serve as a pivotal component and could contribute to the competence of initial learning phase surgeons, achieving comparable levels to experienced surgeons. Regarding training with the Senhance™ Robotic System, structured training is available and substantially helps to improve patient safety.

Another safety feature is the open console setting, which promotes improved team communication between the surgeon and the rest of the team situated in the OR. While the communication is also secured, the ergonomic seating position enhances comfort for the operating surgeon [15], strengthening safety and control measures. This increased focus and communication could contribute to the low number of recorded AEs during the procedures (3 cases, 0.09% of all cases). Further, the AEs were most likely judged as mild. However, a fairly large portion was considered severe (30 cases) and was even found to be SAE (44 cases, 1.4% of all cases). It is well known that in complex surgical procedures, increased SAEs and AEs rates must be anticipated, regardless of the surgical approach chosen. Aligning with this finding, we also need to discuss how robotic surgery is used for especially complex cases in the later stages of the learning curve. Given the total number of cases (3,239), a significant proportion subsequently involved more complicated procedures with thus higher rates of AEs and SAEs. However, an essential finding in this context is that most AEs were judged unrelated to the robotic system. Hence, they most likely occurred in the presence of confounding factors such as the nature of the procedure, underlying diseases or patient characteristics, e.g., risk factors. Finally, only 1 case (0.8%, 0.03% of all cases) was judged as certainly related to the robotic system. Even though this number is fairly small, it highlights that the Senhance™ Robotic System is a minimally invasive procedure operated through a second medium with complex equipment.

From a future perspective, Artificial intelligence (AI) might be a valuable integration into robotic surgery and the Senhance™ Robotic System [16]. Competences such as predicting intraoperative bleeding might assist surgeons in the learning period, potentially enhancing surgeon confidence and patient safety [17]. In addition, AI-driven robotic guidance tools for detecting bowel adhesions or identifying bleeding sources could significantly assist surgeons during procedures. Further advancements in deep learning algorithms may enable intraoperative classification and even diagnosis of cancerous tissue, such as colorectal cancer, leading to greater accuracy and improved patient outcomes [18, 19]. Beyond this, the Internet of Things (IoT) could play a crucial role by seamlessly integrating information from various surgical elements, including the robotic system and the surgeon but also smart surgical instruments, and other medical staff [20]. This interconnected network

could facilitate real-time communication and coordination, enhancing precision, efficiency, and overall surgical safety.

Limitations

Our current study's findings should be considered within the context of its limitations. Firstly, we did not directly compare our data to other robotic systems or to open or laparoscopic approaches. Secondly, patient follow-up data was not included. Finally, patient selection across all centres was likely guided by choosing patients suitable for robotic procedures.

Conclusion

With a substantial sample size of 3,239 patients, this study provides a comprehensive safety evaluation of gastrointestinal, gynaecological and urological procedures conducted across nine European centres during routine clinical practice. The Senhance™ Robotic System is robust and practical for these applications, ensuring safe and secure performance for surgeons and patients.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Competing interests The authors declare no competing interests.

References

1. Rivero-Moreno Y, Echevarria S, Vidal-Valderrama C et al (2023) Robotic surgery: a comprehensive review of the literature and current trends. Cureus 15:e42370
2. Zahid A, Ayyan M, Farooq M et al (2023) Robotic surgery in comparison to the open and laparoscopic approaches in the field of urology: a systematic review. Journal of Robotic Surgery 17:11–29. https://doi.org/10.1007/s11701-022-01416-7
3. de'Angelis N, Schena CA, Moszkowicz D et al (2024) Robotic surgery for inguinal and ventral hernia repair: a systematic review and meta-analysis. Surg Endosc 38:24–46. https://doi.org/10.1007/s00464-023-10545-5
4. Staib L, Poth C, Schilcher F et al (2023) Safety in senhance™ robotic gastrointestinal surgery in 530 patients. Surg Technol Int 42:sti42/1662. https://doi.org/10.52198/23.STI.42.GS1662
5. Stephan D, Darwich I, Willeke F (2020) First clinical use of 5 mm articulating instruments with the senhance® robotic system. Surg Technol Int 37:63–67
6. Guideline IH (2015) Integrated addendum to ICH E6 (R1): guideline for good clinical practice E6 (R2). Current Step 2:1–60
7. SAS Institute Inc (2023) SAS/STAT®. SAS Institute Inc., Cary, NC
8. Farah E, Abreu AA, Rail B, Salgado J, Karagkounis G, Zeh HJ 3rd, Polanco PM (2023) Perioperative outcomes of robotic and laparoscopic surgery for colorectal cancer: a propensity score-matched analysis. World J Surg Oncol 21(1):272. https://doi.org/10.1186/s12957-023-03138-y
9. Abd El Aziz MA, Grass F, Behm KT, D'Angelo AL, Mathis KL, Dozois EJ, Larson DW (2022) Trends and consequences of surgical conversion in the United States. Surg Endosc 36(1):82–90. https://doi.org/10.1007/s00464-020-08240-w
10. Menke V, Kottmann T, Willeke F et al (2023) Learning curves and procedural times in Senhance®-robotic assisted fundoplication: results from 237 consecutive patients undergoing robotic fundoplication in a single center as part of the European TRUST Robotic Surgery Registry Study. Surg Endosc 37:8254–8262. https://doi.org/10.1007/s00464-023-10226-3
11. Koh DH, Jang WS, Park JW et al (2018) Efficacy and safety of robotic procedures performed using the da Vinci robotic surgical system at a single institute in Korea: experience with 10000 cases. Yonsei Med J 59:975–981. https://doi.org/10.3349/ymj.2018.59.8.975
12. Palagonia E, Mazzone E, de Naeyer G et al (2020) The safety of urologic robotic surgery depends on the skills of the surgeon. World J Urol 38:1373–1383. https://doi.org/10.1007/s00345-019-02901-9
13. Wee IJY, Kuo L-J, Ngu JC-Y (2020) A systematic review of the true benefit of robotic surgery: Ergonomics. Int J Med Robot 16:e2113. https://doi.org/10.1002/rcs.2113
14. Avram MF, Lazăr DC, Mariș MI et al (2023) Artificial intelligence in improving the outcome of surgical treatment in colorectal cancer. Front Oncol 13:1116761. https://doi.org/10.3389/fonc.2023.1116761
15. Checcucci E, de Cillis S, Amparore D et al (2023) Artificial intelligence alert systems during robotic surgery: a new potential tool to improve the safety of the intervention. Urol Vid J 18:100221. https://doi.org/10.1016/j.urolvj.2023.100221

16. Mulita F, Verras G-I, Anagnostopoulos C-N et al (2022) A smarter health through the internet of surgical things. Sensors (Basel) 22. https://doi.org/10.3390/s22124577
17. Bousis D, Verras G-I, Bouchagier K et al (2023) The role of deep learning in diagnosing colorectal cancer. Prz Gastroenterol 18:266–273. https://doi.org/10.5114/pg.2023.129494
18. Chlorogiannis DD, Verras G-I, Tzelepi V et al (2023) Tissue classification and diagnosis of colorectal cancer histopathology images using deep learning algorithms. Is the time ripe for clinical practice implementation? Prz Gastroenterol 18:353–367. https://doi.org/10.5114/pg.2023.130337
19. Yuh BE, Ciccone J, Chandrasekhar R et al (2009) Impact of previous abdominal surgery on robot-assisted radical cystectomy. JSLS 13:398–405
20. Kadoch E, Brezinov Y, Levin G et al (2024) The impact of body mass index on robotic surgery outcomes in endometrial cancer. Gynecol Oncol 185:51–57. https://doi.org/10.1016/j.ygyno.2024.01.051